EXHIBIT A

Controlled Substance Primer

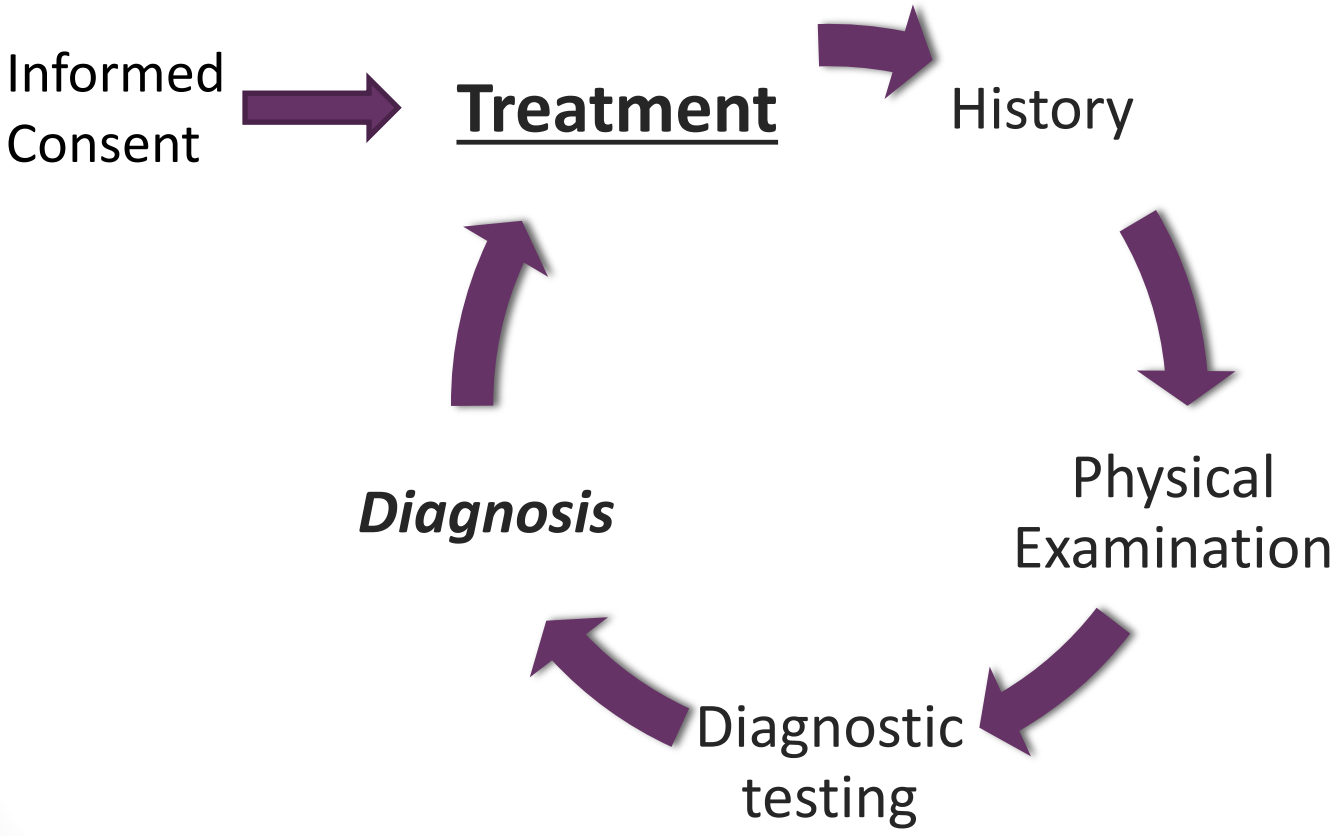
(A Physician's View)

Stephen M. Thomas, M.D., MBA

What is he talking about?

- "Controlled substance"
- "Narcotic"
- "Opioid/opiate"
- "Benzodiazepine"
- "Addiction"
- "Legitimate medical purpose"
- "Usual course of *professional* practice"

Standard Medical Model



Controlled Substances Act (CSA)

- *"Substances are placed in schedules based on:*

1) a currently accepted medical use; 2) their relative abuse potential, and 3) likelihood of causing dependence."

- Schedule **I**: ***No*** currently accepted use.
- Schedule **II**: high potential for abuse/dependence
- Schedule **III**: moderate physical or high psychological dependence
- Schedule **IV**: low relative potential for abuse
- Schedule **V**: low relative, limited quantities

Controlled Substances Act (CSA)

- Schedule **I**: Heroin, MDMA, LSD, PCP
- Schedule **II**: Morphine, **Oxycodone**, Methadone, Hydromorphone
- Schedule **III**: Buprenorphine, Ketamine
- Schedule **IV**: Alprazolam, Diazepam, Soma
- Schedule **V**: Lyrica, Robitussin AC, Lomotil

Pennsylvania Controlled Substances Act

- A physician may dispense controlled substances:

1. "In the usual course of *professional* practice"
2. "Within the scope of the *doctor-patient relationship*"
3. "In accordance with the *accepted treatment principles* of any responsible segment of the medical community"

Guidelines for Controlled Substance Use

- PA Code, Title 49, §16.92

"Prescribing, dispensing and administering"

History, physical examination, document, re-evaluate

- Federation of State Medical Boards,

"Model Policy for the Prescription of Controlled Substances in the Treatment of Pain"

Use carefully, trial, monitor, document, be aware of risk(s)

FSMB, "Model Policy"

- "The Board will consider the use of opioids for pain management to be for a **legitimate medical purpose** if it is based on sound clinical *judgment* and current *best clinical practices*, is appropriately *documented*, and is of *demonstrable benefit* to the patient. To be within the **usual course of professional practice**, a legitimate physician- patient relationship must exist and the prescribing or administration of medications should be *appropriate to the identified diagnosis*, should be accompanied by *careful follow-up monitoring* of the patient's response to treatment as well as his or her *safe use* of the prescribed medication, and should demonstrate that the *therapy has been adjusted as needed* [7,38,43]. There should be *documentation* of appropriate referrals as necessary [36-37]."

Principles of Controlled Substance Prescribing

- *"First, do no harm."—Hippocrates*
- *"Every substance is both a remedy and a poison. The difference is the dose."--Paracelsus, 1538*
- *"The secret of the care of the patient is in caring for the patient."—Sir Francis Peabody, 1927*

What is an “opioid”?

- Opium contains **Morphine**, an opiate.
- An opioid is a man-made Morphine-like drug.
- All opioids act in the same way.
- All opioids are compared to Morphine.
- That comparison is called **Morphine equivalence**

Name	*(Potency)*	*[Brand]*
Morphine	(1)	*[MSContin]*
Hydrocodone	(0.8)	*[Vicodin]*
Oxycodone	(1.5)	*[Percocet]*
Oxymorphone	(3)	*[Opana ER]*
Heroin	(4)	
Hydromorphone	(5)	*[Dilaudid]*
Methadone	*(4-12)*	
Fentanyl	(100)	

The "Morphines" (MME)

(Opioids)

Relative Strength

Benzodiazepines (Xanax, Klonopin, Valium) [IV]
Tramadol (Ultram) [IV]
Amphetamines (Adderall) [II]
Methamphetamine [II]
Barbiturates (Soma) [V]
Cocaine [II]
Cannabinoids/Marijuana [I]
Phencyclidine (PCP) [I]

Other Controlled Substances

Benzodiazepines [IV]

--Xanax is Alprazolam. (1)

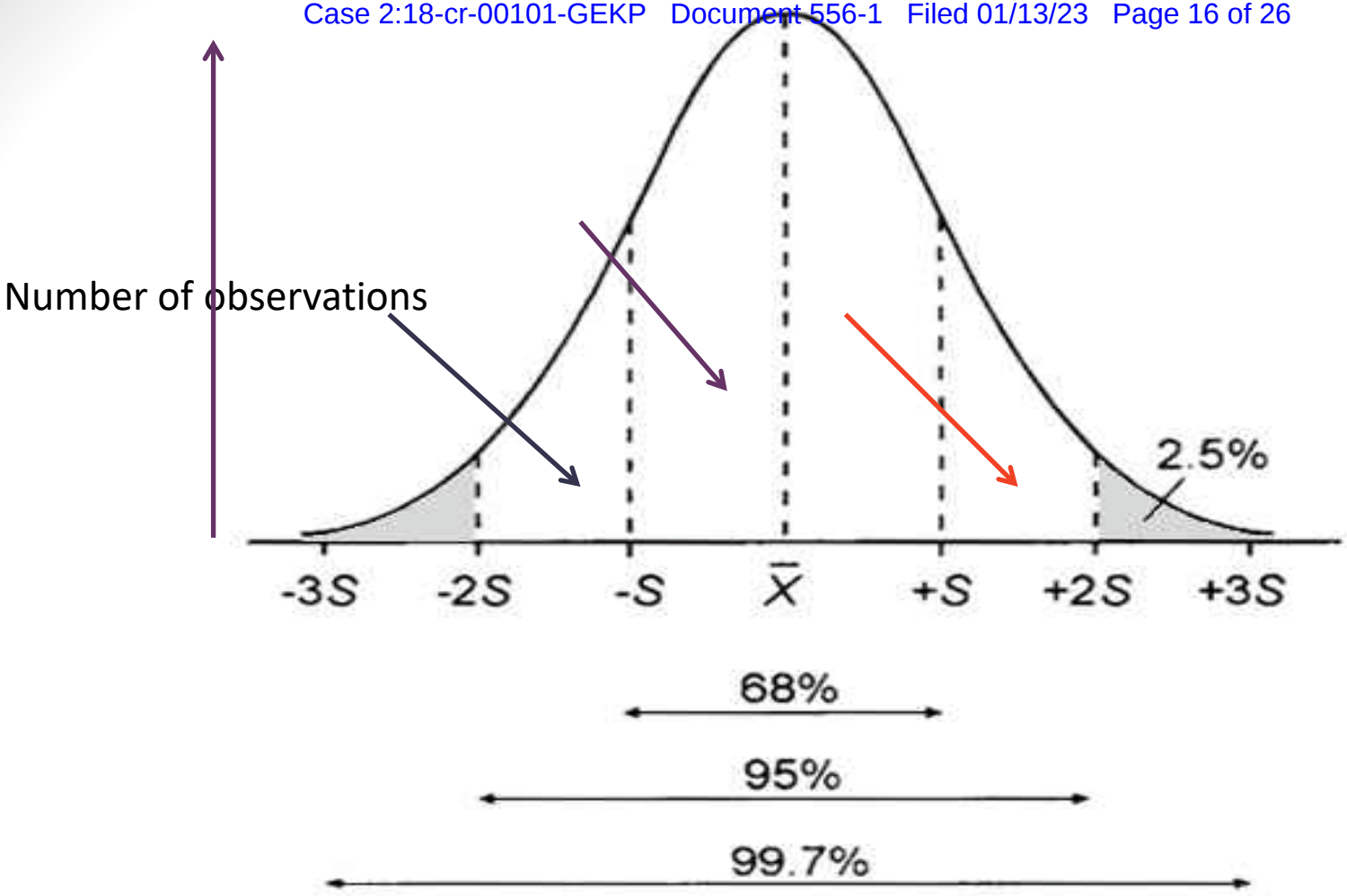
--Valium is Diazepam. (10)

--Klonopin is Clonazepam. (0.5)

--Ativan is Lorazepam. (2)

*By themselves among the safest drugs, combined with opioids increase the overdose rate by **1500**%.*

What's with the two names thing?



How Doctors Think

1. Diagnosis
2. Psychologic Assessment
3. Informed Consent/Agreement
4. Assessment of Pain and Function
5. Trial
6. Reassess: **A**nalgesia, **A**ctivity, **A**dverse, **A**berrant behavior
7. Document

"Universal Precautions in Pain Medicine"

--**Urine**, saliva, sweat, blood and hair can all be tested for the **presence or absence** of drugs.

--Urine is the standard fluid with the greatest amount of data.

--Screening shows the **presence or absence** of the drug, little more, little less.

Drug Screening

- **Initial screening** to determine whether the patient is taking illicit drugs.
- **Follow-up screening** tells if the patient :
  1. Is taking the **prescribed medication**; and
  2. Is using **illicit drugs**.
- **Laboratory** testing is definitive.

Urine Drug Screening

- **Laboratory** testing is definitive.

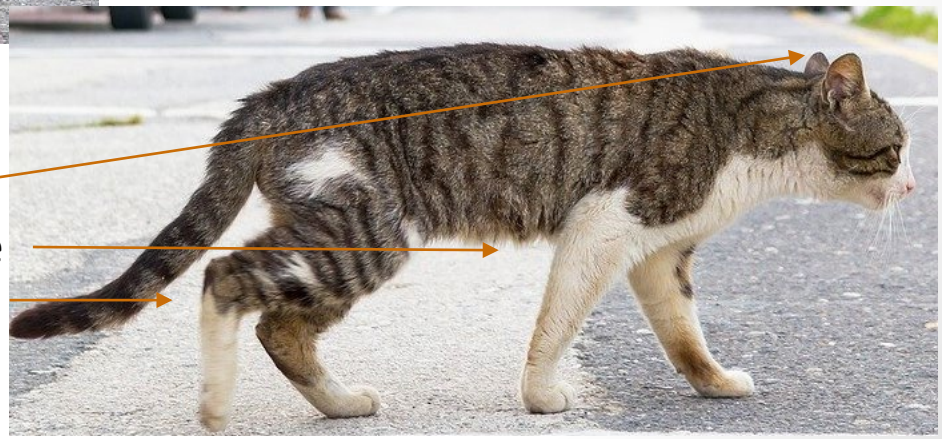
1. The test shows the parent drug and/or metabolites (what the body does with the drug).
2. If the drug is taken the same way then the body does the same thing.
3. If you see something different, something different is happening.

Urine Drug Screening

Oxycodone on the way in…

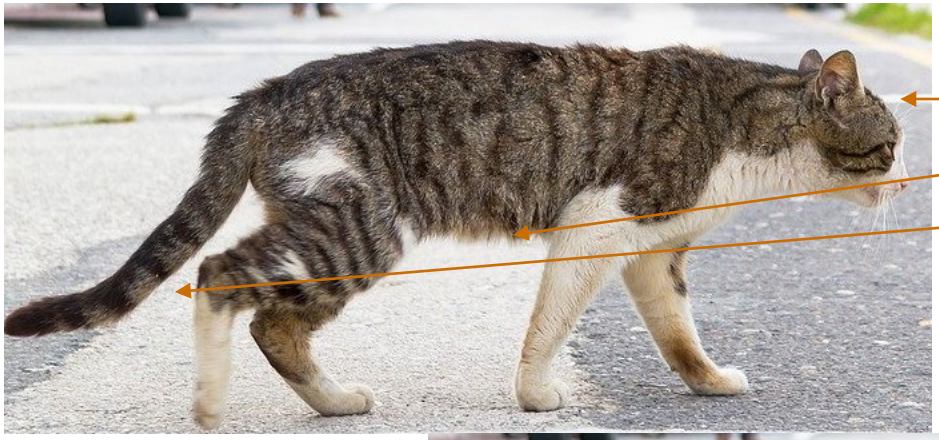
Oxycodone

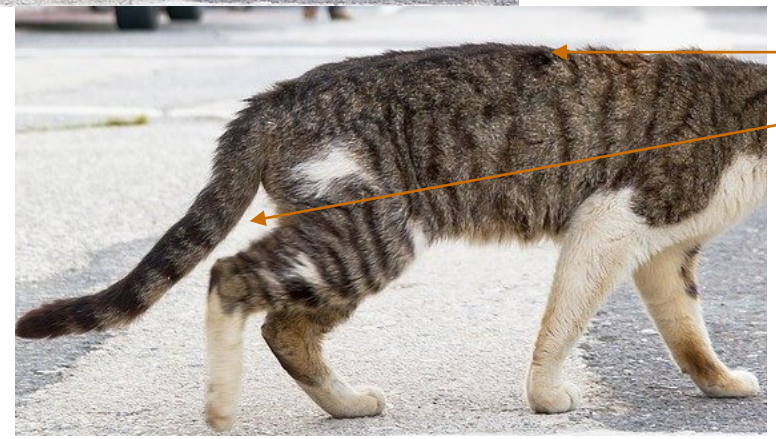
Oxycodone
Noroxycodone

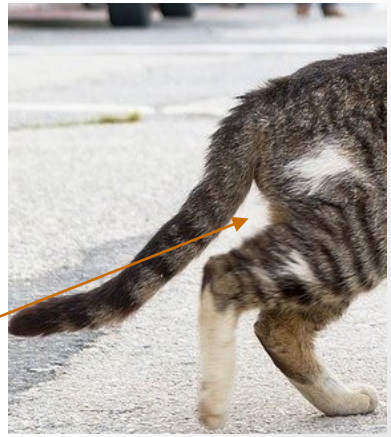


Oxycodone
Noroxycodone
Oxymorphone

Oxycodone on the way out…







A **chronic, relapsing, toxic encephalopathy**, characterized by the compulsive seeking and consumption of the **toxin** involved in the production of the disease.

Addiction

(Thomas' Working Definition)

1. **C**ompulsion
2. **C**raving
3. **C**onsequences
4. **C**ontinued Use despite harm

4 Cs of Addiction

Common Knowledge

CHART

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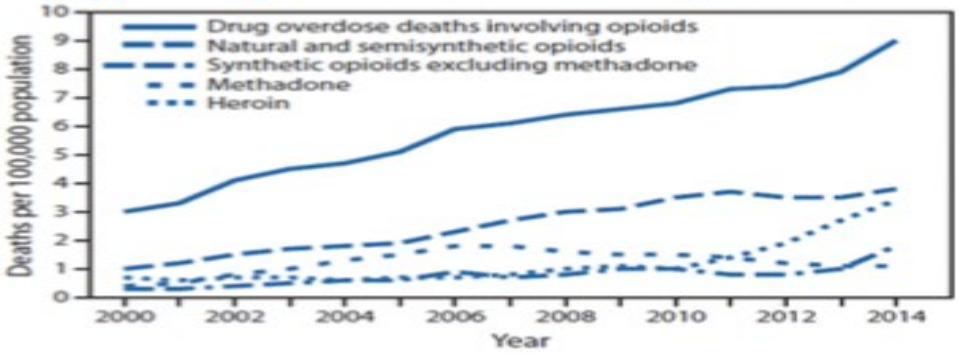
Philadelphia Department of Public Health
Thomas Farley, MD, MPH, Commissioner

The Epidemic of Overdoses From Opioids in Philadelphia

Growth in the use of opioids, including prescription painkillers and heroin, is fueling a nationwide epidemic of deaths from drug overdose. This first issue of *CHART* summarizes the problem nationally and in Philadelphia, and gives recommendations for healthcare professionals and families.

Drug overdose deaths involving opioids by type of opioid — United States, 2000–2014[1]



- According to the Centers for Disease Control & Prevention (CDC), 47,055 people died from drug overdoses in the United States in 2014, for a rate more than double that of 2000.[1]
- Among overdose deaths in 2014, 61% involved opioids.
- Increases in opioid-related deaths resulted from the use and misuse of prescription pain relievers and the use of heroin.
- Since 1999, the number of prescriptions for pharmaceutical opioid pain relievers in the U.S. more than quadrupled.[2]
- People who have misused opioid pain relievers are 19 times more likely than others to start using heroin, even though few people who misuse pharmaceutical opioids become heroin users (4% initiate heroin use within 5 years).[3]

Risks

- 47,005 overdose deaths in 2014.
- 14.8 deaths per 100,000.
- 3.2 deaths per 100,000 (1996).
- 460% increase.

"Trends in Opioid Analgesic Abuse and Mortality in the United States." Dart, et al., N Engl J Med 2015; 372:241-8.